EXHIBIT 43

101st Congress
1st Session

COMMITTEE PRINT

S. PRT.
101-49

PRESCRIPTION DRUG PRICES: ARE WE GETTING OUR MONEY'S WORTH?

A MAJORITY STAFF REPORT

OF THE

SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE

AUGUST 1989

Serial No. 101-D

This document has been printed for information purposes. It does not offer findings or recommendations by this committee.

U.S. GOVERNMENT PRINTING OFFICE
20-721 WASHINGTON : 1989

For sale by the Superintendent of Documents, Congressional Sales Office
U.S. Government Printing Office, Washington, DC 20402

FOREWORD

On July 11, 1989, Congress learned that the Congressional Budget Office (CBO) would soon significantly raise its cost estimate for the new Medicare Catastrophic Coverage Act (MCCA) prescription drug benefit. As a result, many observers now believe that the Congress will not be able to lower premiums for the benefits included in the Act. Moreover, because of the CBO estimate, some Members of Congress have advocated delaying or eliminating the Medicare outpatient drug benefit.

The prescription drug benefit included in the MCCA is viewed by many to be its most important provision, soon to help 9 million older Americans annually to pay drug bills. Prescription drug costs represent the largest out-of-pocket health care expense for three of every four older Americans. It is therefore not surprising that over 15 percent of the elderly patients who require prescriptions report they are unable to pay for their medications.

In light of this cost burden, proposals to reduce insurance protection against the cost of prescription drugs greatly concern older Americans and their advocates. Furthermore, during the last decade, health policymakers of both political parties have concluded that it is both more constructive and compassionate to attempt to address the reasons behind rapidly increasing health care costs than to simply deny benefits to those in need.

The Special Committee on Aging hearing of July 18, together with this staff information paper, represent an attempt to target the reasons behind prescription drug cost increases. This staff report summarizes the findings of the Committee's investigation into prescription drug costs, drug price differentials in domestic and international markets, the relative value of products resulting from drug research and development, and the prices the Medicare program will be paying for its new coverage of prescription drugs.

It is my hope that this information will help interested parties better understand the prescription drug industry and the difficulties of controlling prescription drug price increases. As is the case in most detailed inquiries into a subject, the information that has been gathered leads us to ask additional questions. I intend to hold additional hearings on this subject to help the Congress evaluate options for efficiently providing the oldest and poorest Americans with protection from the high cost of prescription drugs.

David Pryor
Chairman, United States Senate
Special Committee on Aging

TABLE OF CONTENTS

UNITED STATES SENATE

SPECIAL COMMITTEE ON AGING

STAFF INFORMATION PAPER

PRESCRIPTION DRUG PRICES: ARE WE GETTING OUR MONEY'S WORTH?

Executive Summary

Introduction.

Spending for prescription drugs in the United States now accounts for about 7 cents of every health care dollar. Prices charged by prescription drug manufacturers have become important to the public, and the elderly in particular, for the following reasons:

(1) While the public is using about the same amount of drugs today as in 1980, price increases for prescription drugs have increased by 88% from 1981-1988, a period during which the Consumer Price Index increased only 28%;

(2) Though comprising only 12% of the population, older Americans consume approximately 30% of prescription drugs sold in the United States, with over 15% of the elderly who use prescription drugs reporting they are unable to pay for their medications;

(3) Citizens of all ages pay for sharply higher drug prices directly out of pocket at pharmacies, through taxes to support Medicare and Medicaid, and through rising insurance premiums;

(4) Rising drug prices, particularly the high prices of new drugs, are driving State Medicaid program costs and projected Medicare drug benefit expenditures to unsustainable levels, causing the Congress to consider reducing benefits to the elderly and poor, and forcing State legislatures to choose between funding drug benefits or other health care needs of the elderly and poor; and

(5) Small retail pharmacies are being squeezed out of business, caught between rising drug prices and reimbursement limits imposed by public and private payors who won't pay pharmacies fully for the increased cost of drugs they sell.

Responding to these problems, the Chairman of the Special Committee on Aging directed Committee staff to evaluate the appropriateness of prescription drug pricing levels.

In initiating the Committee's investigation, Chairman Pryor sought to approach the problem as consumers generally do when evaluating the price of any product: by taking into account both the value of the product and market prices. Specifically, staff were asked to investigate (a) the relative therapeutic value of the drug products being brought to market by drug manufacturers, and (b) prices actually paid for these products by price-conscious buyers in the marketplace.

The Committee's investigation consisted of analysis of the federal Food and Drug Administration's published assessments of the "therapeutic potential" of hundreds of new drug products introduced to the U.S. market between 1981 and 1988. Committee staff focused on new products made by the 25 largest U.S. prescription drug manufacturers, who account for 45% of new drug introductions and approximately two-thirds of prescription drug sales in the domestic market.

In addition, scores of interviews were conducted with, and pricing data were accumulated from, buyers in the United States domestic market, academic and industry research reports, Wall Street investment analysts, and governmental officials and private agencies overseas, predominantly in the European Economic Community, Canada, and Japan. Data and descriptive material on pricing practices was also obtained from several prescription drug manufacturers themselves.

Summary of Findings

Pertaining to the Value of New Prescription Drug Products

Finding 1: The bulk of research and development by prescription drug manufacturers produces insignificant new compounds that add little or nothing to drug therapies already marketed (Appendix A, graph and tables 1-7).

Finding 2: Prescription drug manufacturers charge the public high prices for new drugs that duplicate existing, and generally less expensive, drug therapies.

Finding 3: Present governmental incentives to spur true innovation by pharmaceutical manufacturers appear to have failed.

Summary of Findings Pertaining to Drug Pricing in Domestic and International Marketplaces

Finding 4: Prescription drug price increases more than tripled the rate of inflation in the economy from 1981 to 1988, as conservatively measured by the Consumer Price Index (CPI) (see Appendix D).

Finding 5: Prescription drug manufacturers have opted to expand their market by charging penthouse prices to compensate for the poverty of their innovation over the past decade.

Finding 6: Citizens of most countries of the world pay less than U.S. consumers for their prescription drugs (see Appendix F).

Finding 7: There are two domestic markets in the U.S. for most big-selling prescription drugs: a price competitive market characterized by deep discounts off the published list price, and a high-priced market where retail customers, Medicare and Medicaid purchase their prescription drugs (see Appendixes G, H & I).

Finding 8: Actions by insurors and Medicaid programs to reduce drug costs by cutting pharmacy reimbursement have hurt pharmacies but have had little effect on prescription drug prices (see Appendixes K and L).

Finding 9: Congress has previously granted the Executive branch authority which may be useful in obtaining fair drug prices when manufacturers refuse to negotiate drug prices or engage in competitive bidding (see Appendix M).

Questions for Further Research

1. How c government at all levels facilitate meaningful innovatio by pharmaceutical manufacturers?

2. How can the Medicaid and Medicare programs achieve the efficiencies in purchasing pharmaceuticals that the Department of Veterans' Affairs has already realized?

3. What, if anything, are foreign governments doing to hold down pharmaceutical prices for their citizenries?

4. Why will some manufacturers negotiate drug prices with some or all buyers, while others maintain a "policy" of not bidding in response to solicitations?

UNITED STATES SENATE

SPECIAL COMMITTEE ON AGING

STAFF INFORMATION PAPER

PRESCRIPTION DRUG PRICES: ARE WE GETTING OUR MONEY'S WORTH?

Findings Pertaining to

the Value of New Prescription Drug Products

Finding 1: **The bulk of research and development by prescription drug manufacturers produces insignificant new compounds that add little or nothing to drug therapies already marketed** (Appendix A, graph and tables 1-7).

- While important new pharmaceuticals are discovered each year, the top 25 companies introduced to the market just 12 "important" new drugs in the eight years from 1981-88 (see Appendix A, Table 7).

- Eighty-four percent (84%) of the 348 new drugs brought to market by the 25 largest U.S. drug manufacturers between 1981 and 1988 were evaluated by the federal Food and Drug Administration (FDA) as "C"-rated, having "little or no" potential for therapeutic gain over existing drug therapies.

- For every "important" new drug marketed by the 25 largest U.S. drug manufacturers, 24 "C"-rated new drugs, those with "little or no" therapeutic potential to improve on existing drug therapies, were brought to market.

- Of the 348 new drugs marketed by the top 25 firms between 1981 and 1988, only 91 were "New Molecular Entities", new drugs made of molecules never previously approved by FDA for use by human beings. Of these, sixty percent (60%) were evaluated by the FDA as "C"-rated, making "little or no" contribution to existing drug therapies.

- The federal Food and Drug Administration evaluations of new drug therapeutic potential are based on the following official definitions (Source: FDA New Drug Evaluation Statistical Report):

"A" Rated - "Important Therapeutic Gain - The drug may provide effective therapy or diagnosis for a disease not adequately treated or diagnosed by any marketed drug, or provide improved treatment of a disease through improved effectiveness or safety (including decreased abuse potential)."

"B" Rated - "Modest Therapeutic Gain - The drug has a modest, but real, potential advantage over other available marketed drugs - e.g., greater patient convenience, elimination of an annoying but not dangerous adverse reaction, potential for large cost reduction, less frequent dosage schedule, useful in specific subpopulation of those with disease (e.g., those allergic to other available drugs), etc."

"C" Rated - "Little or No Therapeutic Gain - The drug essentially duplicates in medical importance and therapeutic usage one or more already marketed drugs."

Finding 2: Prescription drug manufacturers charge the public high prices for new drugs that duplicate existing, and generally less expensive, drug therapies.

- When FDA classifies a new drug for its "therapeutic potential" (resulting in an "A", "B", or "C" rating), implicit in its rating is consideration of whether the new drug has the "potential for large [treatment] cost reduction". Therefore, an FDA "C"-rating means the new drug fails to provide significant economic advantages to the patient, compared to already marketed drugs used for the same ailment.

- Hambrecht and Quist, Inc., Wall Street investment analysts, noted in 1988 that "new drugs are priced higher, in most cases substantially higher, than older medicines, and this trend will continue."

- Committee staff evaluated manufacturer pricing patterns for four anti-ulcer drugs introduced during the 1980s. All four drugs are based on new patented molecules, but work similarly in the body (all classified as "H2 Antagonists"). Though the three newest drugs were "C"-rated by the FDA for offering "little or no therapeutic gain" over the first drug, each was priced higher than the innovator product (see graph at Appendix C).

  When Glaxo Holdings, Inc. introduced the anti-ulcer drug Zantac (Ranitidine) to the market in July 1983, it priced this "C"-rated product 46% higher in cost per day of therapy than the innovator brand, Tagamet (Cimetidine), made by SmithKline Beckman Corp.

  When Merck and Company introduced the anti-ulcer drug Pepcid (Famotidine) to the market in November 1986, it priced this "C"-rated product 7% higher than the innovator brand, Tagamet. Tagamet's price had by then risen 48% since its first competitor, Zantac, was introduced.

  When Eli Lilly and Company introduced the anti-ulcer drug Axid (Nizatidine) to the market in May 1988, it priced this "C"-rated product 13% higher than the innovator brand, Tagamet. Tagamet's price had by then risen 64% (about 12% per year) since its first competitor, Zantac, was introduced.

- One reason for the high prices of "C"-rated drugs may be manufacturers passing on to consumers the high cost of research and development (R&D). U.S. pharmaceutical manufacturers spent at least $7 billion, and as much as $37 billion, from 1981 through 1988 for R&D of new drugs with little or no potential to improve on already marketed drug treatments.

  This estimate is based upon advertising by drug makers asserting that it costs $125 million for R&D needed to bring "a new drug" to market (see Appendix B). However, the industry's claim is based on research into R&D costs for the small fraction of new drugs known as "New Molecular Entities" -- not for all "new drugs". Between 1981-88, of their total output of 348 new drugs, the top 25 U.S. drug manufacturers produced only 91 NMEs (26%).

  The $125 million represented by the industry as the cost of developing "a new drug" may not accurately represent the cost of R&D invested in the vast majority (74%) of new drugs brought to market. Experts contacted by Committee staff disagreed as to whether firms spend more, or less, for R&D on the bulk of new drugs that are not "New Molecular Entities".

  Based upon the industry's published figure for R&D costs for "a new drug", between 1981-88 the top 25 U.S. drug makers spent, and passed on to consumers, about $37 billion for R&D to produce 292 new drugs with "little or no potential for therapeutic gain" over existing drug therapies. Of this total, approximately $7 billion was spent to bring to market 54 "New Molecular Entities" with "little or no potential for therapeutic gain" over existing drugs.

  A "New Molecular Entity" (NME) is an active ingredient molecule significantly different in structure than any previously approved by FDA for use in human beings.

Finding 3: Present governmental incentives to spur true innovation by pharmaceutical manufacturers appear to have failed.

- In the United States, numerous subsidies in the form of tax credits are granted at the federal level to R&D based manufacturers without regard to the track record of meaningful innovation of the firms receiving tax subsidies.

  The federal R&D tax credit alone, codified at Section 41 of the Internal Revenue Code, was worth an average of about $14 million to each of the firms surveyed by the Committee during the period 1981-1988.

- Other countries, such as Japan, have sought to encourage innovation by manufacturers by paying higher government reimbursement rates for new compounds, but appear to have no means of distinguishing "me-too" drugs from those making a significant contribution over existing drug therapies.

Findings Pertaining to Drug Pricing in Domestic and International Marketplaces

Finding 4: Prescription drug price increases more than tripled the rate of inflation in the economy from 1981 to 1988, as conservatively measured by the Consumer Price Index (CPI) (see Appendix D).

- Only half of the increase in prescription drug prices during the period 1980-87 is attributable to general inflation in the economy, according to analysis prepared for the Special Committee on Aging by researchers at the congressional Office of Technology Assessment.

- According to a June 27, 1989 draft report prepared by the Health Care Financing Administration (HCFA) of the U.S. Department of Health and Human Services, prescription drug prices charged by manufacturers (as measured by the Producer Price Index, or PPI) rose an average of 10.1% per year between 1981 - 1986, when the Consumer Price Index rose only 4.2%.

  During 1987 and 1988, HCFA found the PPI for prescription drugs rose 9.6% and 7.9% respectively, while the CPI increased 4.4% in each year.

  The stock research firm Salomon Brothers projected in its Pharmaceuticals Prescription Pricing Report for May 1989 that drug prices will rise 8.6% in 1989.

- Both PPI and CPI prescription drug price indexes are conservative measures of drug price inflation because they underestimate the impact on prescription drug prices of the introduction into the market of new, higher-priced drugs.

  Investment analysts at Hambrecht and Quist, Inc. noted in 1988 that "price index data do not properly show what is happening to prices of new pharmaceuticals....Since price indices do not adjust for newly introduced products, other than on a substantially lagged basis, this factor is ignored in presenting price data."

Finding 5: Prescription drug manufacturers have opted to expand their market by charging penthouse prices to compensate for the poverty of their innovation over the past decade.

- Unlike previous decades, during the 1980s drug manufacturers have been unable to expand their markets significantly by inventing new drugs for ailments lacking safe or effective treatment.

  From 1980 through 1987 the volume of drugs used, and complexity of the mix of drugs used, changed little. Only 3% of the increase in total spending on prescription drugs was due to increased use of drugs by the public, according to analysis by researchers at the congressional Office of Technology Assessment (OTA) (see Appendix E). The same analysis concluded higher prices accounted for 97% of increased spending for prescription drugs from 1980 - 1987.

  Analysis by the Congressional Budget Office, based on new data from the Department of Health and Human Services, confirms that drug prices -- rather than increased use of drugs -- are the primary force behind rapidly rising expenditures by the elderly for prescription drugs during the decade of the 1980s.

- Investment analysts at Le Rothschild, Unterberg, Towbin Industry Research observed in a 1986 study of the pharmaceutical industry that "[s]ince the late 1970s--but most noticeably in the last three years--pricing has become the major force in generating revenue growth....In effect, the domestic industry has become almost totally dependent on price increases to generate sales growth..."

- In 1987 The Economist noted that "slowing down in volume growth in existing markets would not be so important if there were dozens of exciting new drugs in new therapeutic areas coming on to the market in the next year or so; but there are not. Most recent product launches have been me-toos, which do not find new markets but simply provide substitutes for older products...Drug companies have therefore been forced to rely on price increases on older products to boost their profits."

- Drug manufacturers have been rewarded with high profits for relying on price increases during a period of stagnant innovation. Investment analysts Hambrecht and Quist, Inc. stated in 1988 that "return on equity for the pharmaceutical industry has been consistently above that of the [Standard and Poors] 400, the main industrial sector of the market. If anything, this gap has widened over the past ten years..."

Finding 6: Citizens of most countries of the world pay less than U.S. consumers for their prescription drugs.

- An analysis of prescription drug prices in seven European countries, published in 1988 by the Farmindustria, the Italian pharmaceutical manufacturers association, shows that U.S. consumers pay up to 5 times what European citizens pay for brand name drugs. (See Chart, Appendix F.)

  Only the citizens of Japan pay higher prices for prescription drugs than Americans. However, unlike the federal and State governments in the United States, the Japanese government has slashed drug prices by an average of 50% over the past five years in response to this problem.

Finding 7: There are two markets in the United States for most big-selling prescription drugs: a price-competitive market characterized by deep discounts off the published list price, and a high-priced market, where retail customers, Medicare and Medicaid purchase their prescription drugs.

- Manufacturers have in the past sought to justify high prices for patented drugs with the assertion that R&D costs must be recouped before the drug's patent expires, subjecting it to price competition from generic drugs.

  However, rather than engaging in price competition, manufacturers typically continue to raise brand name drug prices even after a patent expires, seemingly without regard to one or more generic drugs entering the market as "competitors" (see Appendix G).

  Manufacturers appear to find it necessary to compete with generics on the basis of price only where a buyer has insisted on obtaining better prices, and has organized its purchasing process to include competitive bidding and/or negotiating prices with manufacturers.

- The Department of Veterans' Affairs (DVA, formerly the Veterans Administration) has an extremely successful program in which it negotiates prices with manufacturers of single source drugs and puts multiple source drugs out to bid to several manufacturers (see Appendices H and I).

  DVA achieves an average discount of 41% off the manufacturer's published "Average Wholesale Price" (AWP) for single source drugs (those still under patent), and an average of 67% off the published AWP for multiple source drugs.

  According to DVA, these savings are obtained by DVA through its Federal Supply Schedule (FSS) procurement scheme, in which the drug manufacturer remains responsible for delivering the product "through commerical distribution channels" to DVA's hospitals and outpatient pharmacies.

  Much deeper discounts are achieved by DVA in its Depot system, in which DVA itself is responsible for warehousing, storage, and distribution of the drug products it purchases in large quantities.

- The State of Kansas Medicaid program embarked on a program similar to DVA's three years ago, saving a few hundred thousand dollars per year, but manufacturers' refusal to bid or negotiate has cost the State millions of dollars.

  Kansas Medicaid administrators estimate the State's taxpayers could save up to an additional $500,000/year if manufacturers of the four currently marketed anti-ulcer drugs known as "H2 antagonists" would respond to offers with bids.

  Kansas officials believe State and federal governments could save hundreds of millions of dollars if Congress were to put into place a national bidding and negotiating program under the Medicaid program.

- Hospitals, Health Maintenance Organizations, and nursing homes that contract with wholesalers to purchase prescription drugs from a predetermined list are able to achieve discounts of up to 99% off the manufacturer's published "Average Wholesale Price" (AWP), even for brand name products (see Appendices H and I).

These contract prices are made available to hospitals by some manufacturers irrespective of the size or for-profit status of an institution.

In addition to offering deep discounts to contract buyers, manufacturers will lock in contract prices, sparing selected buyers from drug price increases for periods of up to a year.

- Drug manufacturers are more likely to offer a given buyer or group of buyers price discounts significantly below the published AWP when:

  (1) the buyer can reliably provide increased market share to a manufacturer as part of a deal involving a reduced price (hospitals gain leverage by focusing their buying on selected drugs listed in a formulary);

  (2) the buyer is associated with a "captive" panel or concentration of physicians and patients, such as a hospital, nursing home, HMO or other managed care plan that provides a marketing advantage by getting physicians and/or patients used to relying on a given product (formularies magnify the marketing advantage);

  (3) the buyer assumes substantial responsibilities for the distribution of drug products; and

  (4) it takes fewer manufacturer sales personnel to service a large buyer.

- Independent retail pharmacists are typically able to purchase prescription drugs from wholesalers (or direct from the manufacturer) for discounts of about 13% off the manufacturer's published AWP, paying a higher price than any other provider in the market. To obtain deeper discounts, retail pharmacists have begun in recent years to establish buying groups to amass buying power.

  Buying groups whose member pharmacies adhere to the recommended list of drug products negotiated by the group are more successful in obtaining discounts.

  With few exceptions, pharmacy buying groups are unable to secure significant discounts from manufacturers on single source (patented) drugs, and find it difficult to obtain significant reductions in the price of brand name drugs even after patent expiration.

  Some manufacturers make it their "policy" not to supply bids when approached by pharmacy buying groups, including groups representing thousands of pharmacies in many States, possibly violating federal anti-trust law (see Appendix J).

Finding 8: Actions by insurors and Medicaid programs to reduce drug costs by cutting pharmacy reimbursement have hurt pharmacies but have had little effect on prescription drug prices.

- In response to rising drug costs, insurors and Medicaid programs have sought to limit the size of reimbursement increases paid to pharmacists in recent years.

  State laws and insuror policies generally recognize the manufacturer's published AWP as the reimburseable amount for the drug product itself, but there is no equivalent mechanism for identifying increases in pharmacist salaries and overhead.

  The combined effect of rapidly rising wholesale prescription drug prices paid by pharmacists, and reimbursement limits imposed by insurors and Medicaid, are hurting pharmacists' profitability (see Appendixes K and L).

Finding 9: Congress has previously granted the Executive Branch authority which may be useful in obtaining fair drug prices when manufacturers refuse to negotiate drug prices or engage in competitive bidding.

- Direct business negotiations over drug prices between pharmaceutical manufacturers and third party payors (such as Medicaid, Medicare, and private insurors) could remove pharmacies from the middle of drug price disputes between payors and manufacturers and address more directly the root cause of rapidly rising drug spending.

- Under federal law, if the United States government is unable to obtain a reasonable price for a patented product, it may arrange for another manufacturer to produce the product. If a valid patent is thereby infringed, the patent-holder may obtain payment of royalties from the government by filing a complaint in the United States Court of Claims. (See Appendix M, memo from American Law Division of the Congressional Research Service.)

  In such an action, if the patent is held to be valid, the Court will determine "reasonable and entire compensation" (royalties) to be paid to the patent-holder by the government, based on factors including market prices previously paid for the product, licensing fees (if any) for the product, and the actual cost of manufacturing the product.

APPENDIX A

THE "ME-TOO" FACTOR:

Therapeutic Contribution of New Drugs Introduced

Between 1981 and 1988 By the Top 25 U.S. Drug Makers

SUMMARY

Committee staff reviewed published federal Food and Drug Administration (FDA) data describing the agency's ranking by therapeutic potential of all new drugs approved between 1981 and 1988. There were 776 new drugs approved by FDA, according to the FDA published accounts for this period.

For a detailed analysis, Committee staff evaluated FDA rankings of the new drugs brought to market by the top 25 manufacturers (ranked by sales) in the United States. These top 25 firms accounted for:

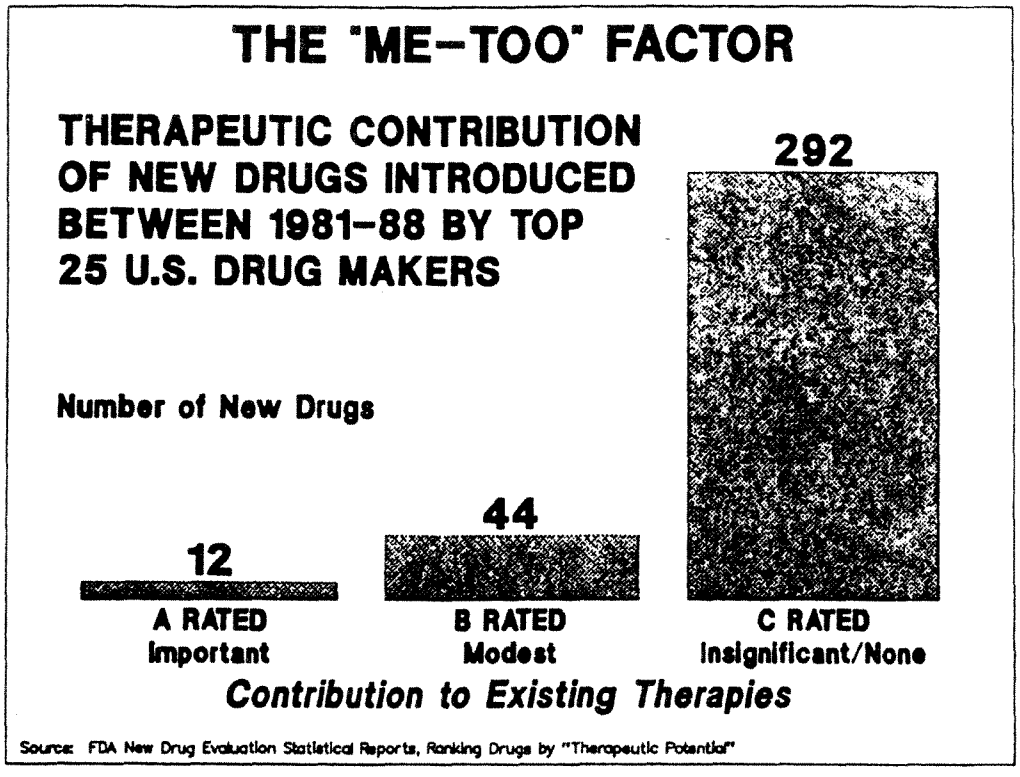
45% of all new drugs approved between 1981 and 1988;

39% of "A"-rated or "important" new drugs;

47% of "B"-rated drugs, those with "modest" potential for therapeutic gain compared with existing drug therapies;

45% of "C"-rated or drugs with "little or no potential for therapeutic gain" compared with existing drug therapies.

[See Next 8 Pages for Graph and Tables in Appendix A.]



APPENDIX A, TABLE 1

THE "ME-TOO" FACTOR:

FDA RATINGS OF NEW DRUGS FOR THERAPEUTIC POTENTIAL

All New Drugs Introduced

By 25 Largest U.S. Rx Drug Manufacturers 1981-88

	Potential Contribution to Existing Therapies			
	A Rated - Important	B Rated - Modest	C Rated - Little/None	Total
Number of New Drugs	12	44	292	348
Percent of New Drugs	3%	13%	84%	100%

(Source: FDA New Drug Evaluations Statistical Reports, Ratings of New Drugs by Therapeutic Potential).

APPENDIX A, TABLE 2

NEW MOLECULAR ENTITIES (NMEs) INTRODUCED

BY 25 LARGEST U.S. Rx DRUG MANUFACTURERS, 1981-1988

	Potential Contribution to Existing Therapies			
	A Rated - Important	B Rated- Modest	C Rated - Little/None	Total
Number of NMEs	7	29	54	90
Percent of NMEs	8%	32%	60%	100%

(Source: FDA New Drug Evaluations Statistical Reports, Ratings of New Drugs by Therapeutic Potential).

APPENDIX A, TABLE 3

TOP 25 MANUFACTURERS COMPARED TO ALL MANUFACTURERS:

FREQUENCY OF PRODUCTION AND THERAPEUTIC IMPORTANCE

OF NEW DRUGS CLASSIFIED AS "NEW MOLECULAR ENTITIES" 1981-88

	Contribution to Existing Therapies			
	A Rated - Important	B Rated - Modest	C Rated - Little/None	Total
Number of New Molecular Entities by Top Companies (excluding diagnostic drugs and vaccines)	7	30	54	91
Percentage of New Molecular Entities by Top Companies	8%	33%	59%	100%
Number of New Molecular Entities by All Companies (excluding diagnostic drugs and vaccines)	23	55	85	163
Percentage of New Molecular Entities by All Companies	14%	34%	52%	100%

(Source: FDA New Drug Evaluations Statistical Reports, Ratings of New Drugs by Therapeutic Potential).

APPENDIX A, TABLE 4

TOP 25 MANUFACTURERS' ANNUAL PRODUCTION OF NEW DRUGS GROUPED BY FDA RATING OF POTENTIAL FOR THERAPEUTIC GAIN

(Number and Percentage of Total)

Year	Therapeutic Potential Rating		
	A	B	C
1981	2 4%	11 23%	35 73%
1982	2 5%	2 5%	35 90%
1983	1 4%	- -	25 96%
1984	- -	8 13%	54 87%
1985	1 2%	6 13%	39 85%
1986	2 3%	11 18%	48 79%
1987	1 3%	4 11%	31 86%
1988	3 10%	2 7%	25 83%
Subtotals:	12 3%	44 13%	292 84%
Total # New Drugs (1981-88)			348 100%

(Source: FDA New Drug Evaluations Statistical Reports, Ratings of New Drugs by Therapeutic Potential).

APPENDIX A, TABLE 5

NEW DRUGS FROM TOP 25 DRUG COMPANIES AS PROPORTION OF NEW DRUGS FROM ALL COMPANIES, 1981-88

Number and Percentage of All New Drugs

Year	Companies	A	B	C	Total
1981	All	3	17	76	96
	Top	2 (67%)	11 (65%)	35 (46%)	48 (50%)
1982	All	7	7	97	111
	Top	2 (29%)	2 (29%)	35 (36%)	39 (35%)
1983	All	5	3	86	94
	Top	1 (20%)	---	25 (29%)	26 (28%)
1984	All	2	15	125	142
	Top	---	8 (53%)	54 (43%)	62 (44%)
1985	All	5	17	78	100
	Top	1 (20%)	6 (35%)	39 (50%)	46 (46%)
1986	All	2	18	78	98
	Top	2 (100%)	11 (61%)	48 (63%)	62 (62%)
1987	All	2	10	57	69
	Top	1 (50%)	4 (30%)	31 (54%)	36 (52%)
1988	All	5	7	54	66
	Top	3 (60%)	2 (29%)	25 (46%)	30 (45%)
Total: All		31	94	651	776
Total: Top		12 (39%)	44 (45%)	292 (45%)	348 (45%)

(Source: FDA New Drug Evaluations Statistical Reports, Ratings of New Drugs by Therapeutic Potential).

APPENDIX A, TABLE 6

INDIVIDUAL DRUG MANUFACTURER TRACK RECORD:

NUMBER OF THERAPEUTIC BREAKTHROUGHS 1981-88

Company	FDA Rating for Therapeutic Potential A (%)	B (%)	C (%)	Total
1. Abbott	1 (11)	4 (4)	103 (95)	108
2. Bristol	3 (60)	2 (20)	5 (50)	10
3. Ciba-Geigy	1 (8)	2 (15)	10 (77)	13
4. Glaxo	-	3 (14)	18 (86)	21
5. Lederle	-	1 (14)	6 (86)	7
6. Lilly	-	4 (20)	6 (80)	20
7. Mead	-	-	1 (100)	1
8. Merck	3 (11)	6 (21)	19 (68)	28
9. Merrell	-	2 (50)	2 (50)	4
10. Pfizer	-	1 (13)	7 (88)	8
11. Roche	1 (7)	5 (33)	9 (60)	15
12. Robins	-	1 (17)	5 (83)	6
13. Roerig	-	-	2 (100)	2
14. Rorer	-	1 (100)	-	1
15. Ross	-	-	-	-
16. Schering	1 (3)	3 (10)	25 (86)	29
17. Searle	-	-	8 (100)	8
18. SmithKline	-	2 (40)	3 (60)	5
19. Squibb	-	3 (15)	17 (85)	20
20. Syntex	-	2 (20)	8 (80)	10
21. Upjohn	2 (17)	-	10 (83)	12
22. Warner	-	-	4 (100)	4
23. Whitehall	-	1 (50)	1 (50)	2
24. Winthrop	-	1 (14)	6 (86)	7
25. Wyeth	-	-	7 (100)	7
Total	12 (3)	44 (13)	292 (84)	348 (100)

(Source: FDA New Drug Evaluations Statistical Reports, Ratings of New Drugs by Therapeutic Potential).

APPENDIX A, Table 7

LIST OF ALL "IMPORTANT" ("A"-RATED) NEW DRUGS INTRODUCED

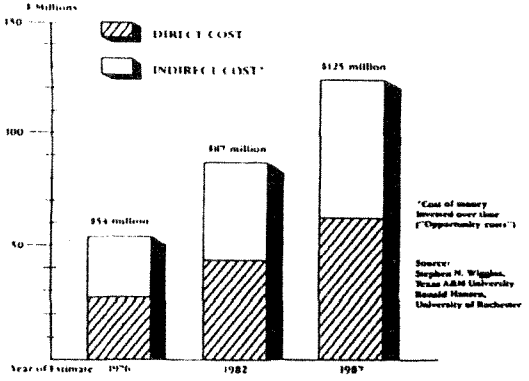
BY THE TOP 25 U.S. PRESCRIPTION DRUG MANUFACTURERS 1981-88

	NAME OF NEW DRUG	INDICATION (USE)
1.	Accutane (Isotretinoin)	Severe acne
2.	Alprostadil (Prostin VR)	Heart problems in premature babies
3.	Blocadren (Timolol)	High blood pressure, Post-heart attack treatment
4.	Cardioplegic Solution	Heart surgery
5.	Cytotec (Misoprostol)	Preventing drug-induced gastric ulcers
6.	Ifex (Ifosfamide)	Cancer
7.	I.V. Indocin (Indomethacin)	Heart problems in premature babies
8.	Lamprene (Clofazimine)	Leprosy
9.	Mevacor (Lovastatin)	High cholesterol
10.	Rogaine (Minoxidil)	Hair growth stimulant
11.	VePesid (Etoposide) (Intravenous solution)	Cancer
12.	VePesid (Etoposide) (Oral capsule)	Cancer

(Source: FDA New Drug Evaluations Statistical Reports, Ratings of New Drugs by Therapeutic Potential).

APPENDIX B

INNOVATION IN MEDICINES #2 In a Series



Cost of Developing a New Drug Exceeds $125 Million

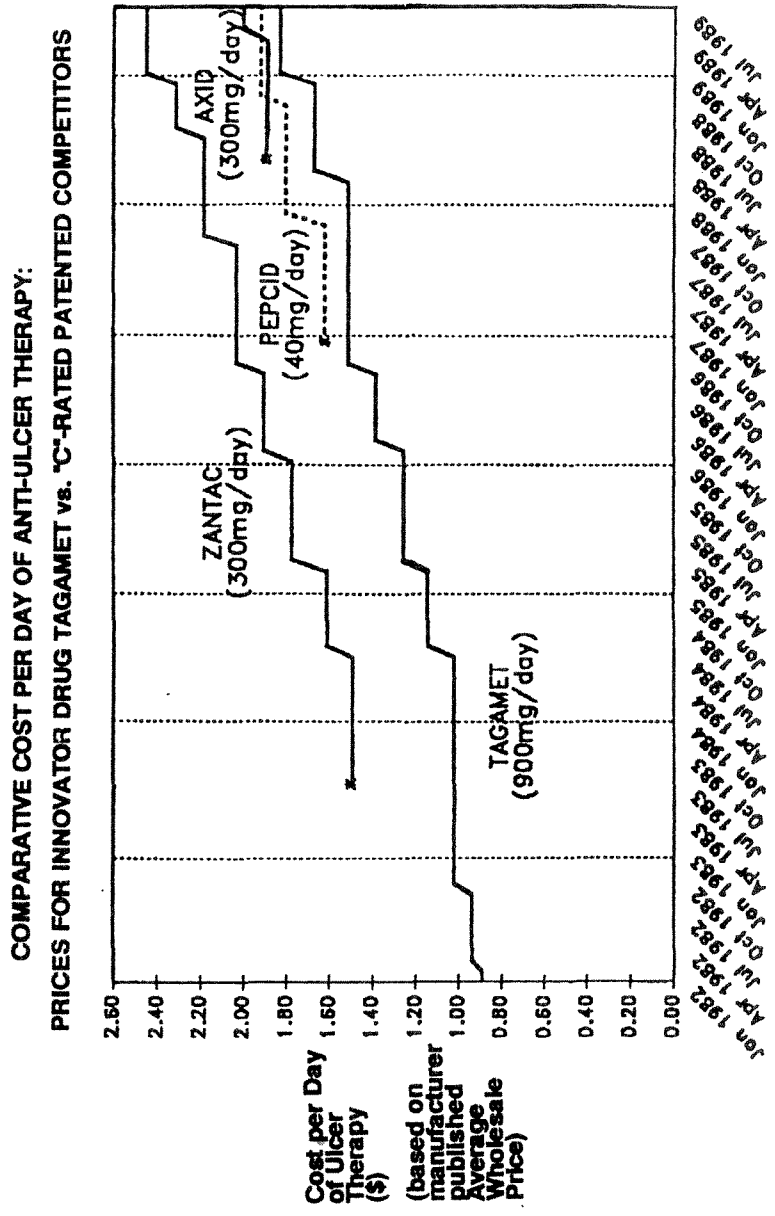
Costs are escalating because of the growing complexity of modern medicines and the 7 to 10 years necessary to move a new medicine from discovery through testing, development and FDA approval

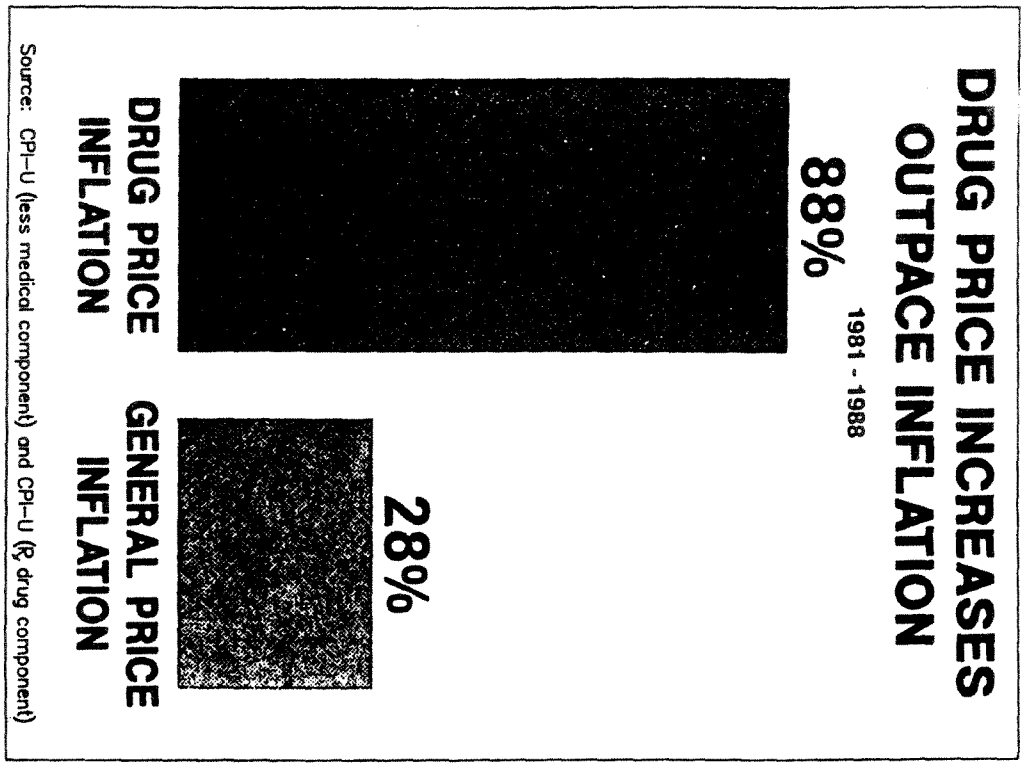
Pharmaceutical Manufacturers Association

1100 Fifteenth Street, N.W., Washington, D.C. 20005

America's Pharmaceutical Research Companies

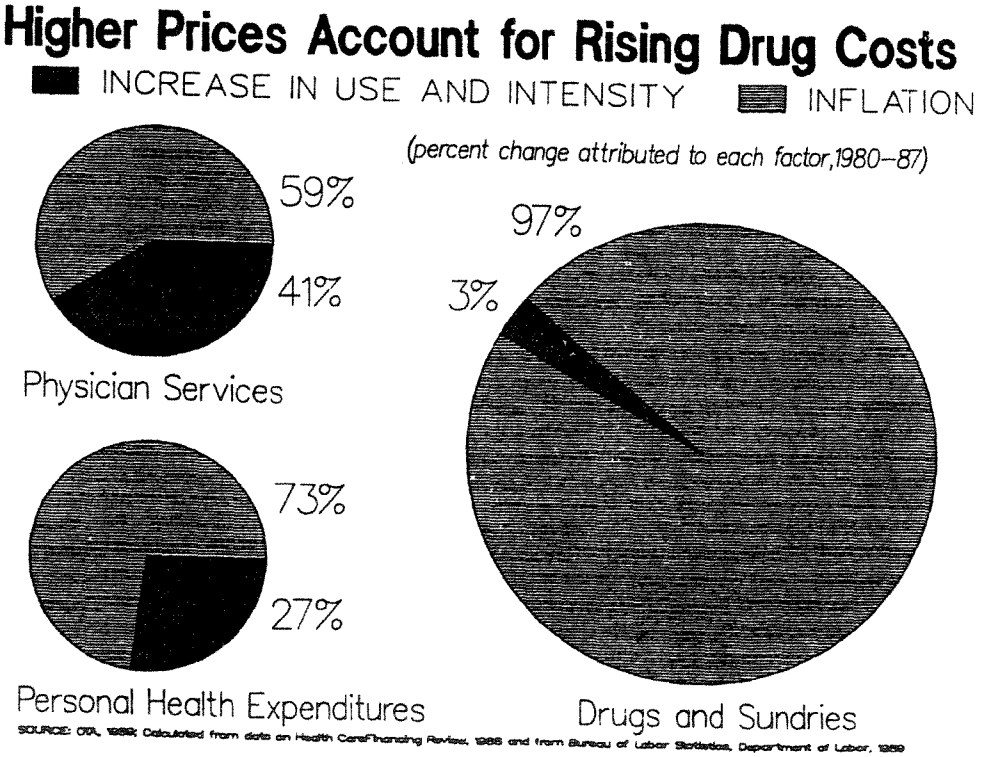
APPENDIX C





APPENDIX D

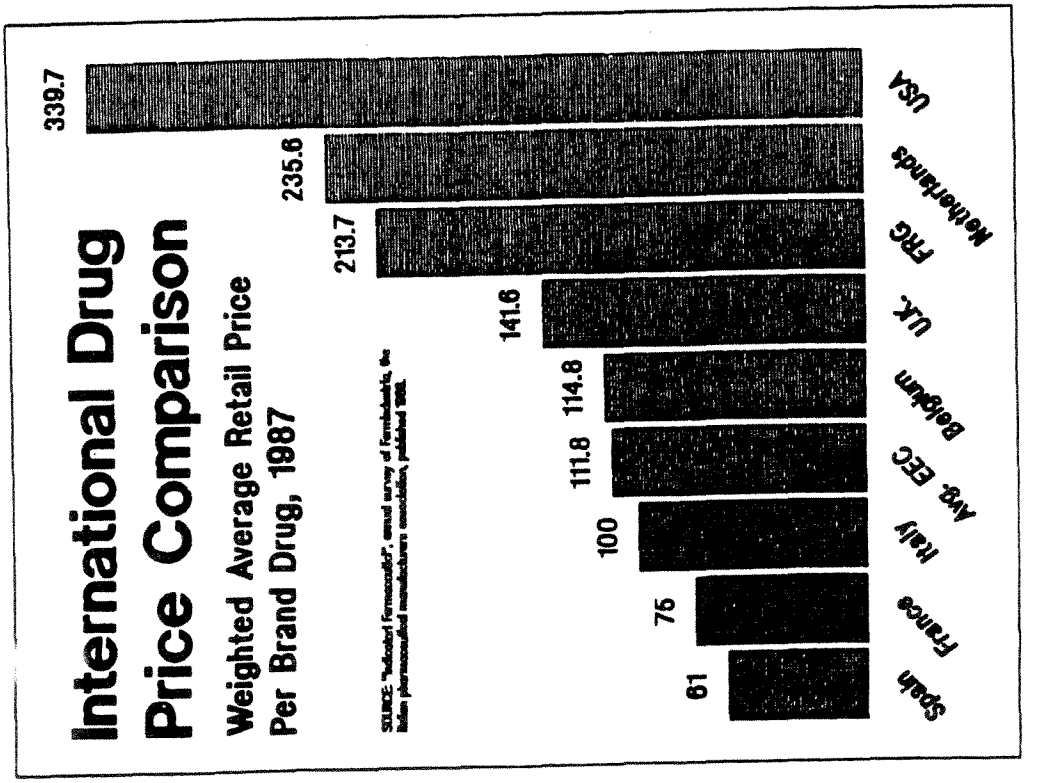
26



APPENDIX E

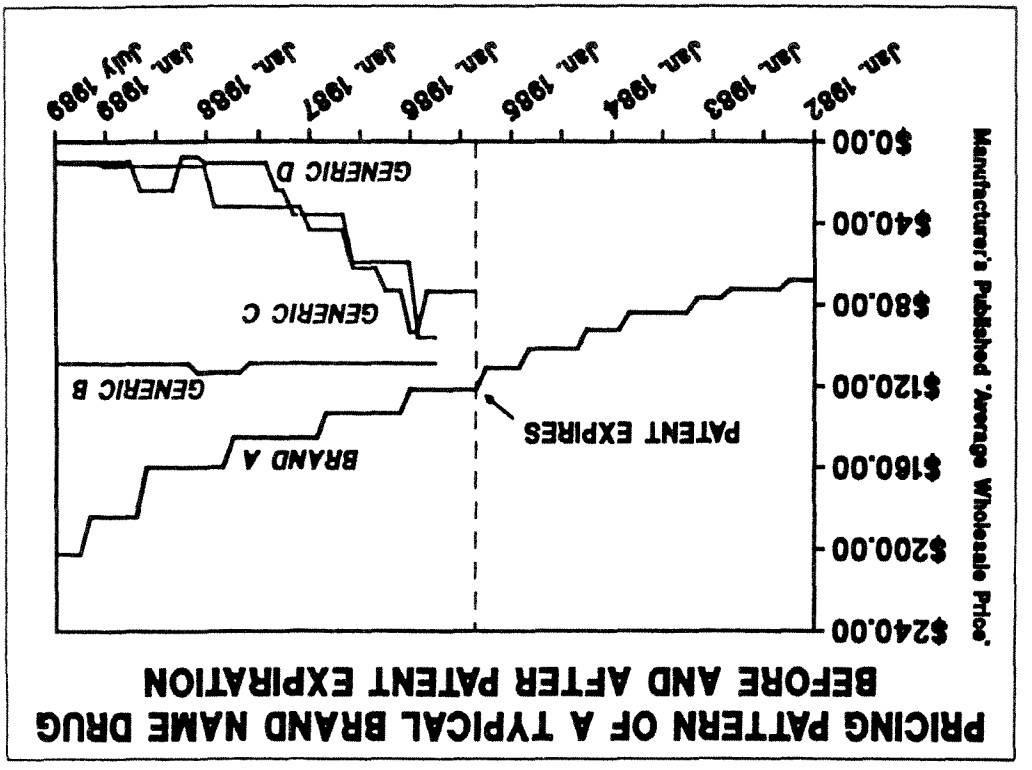
27

APPENDIX F



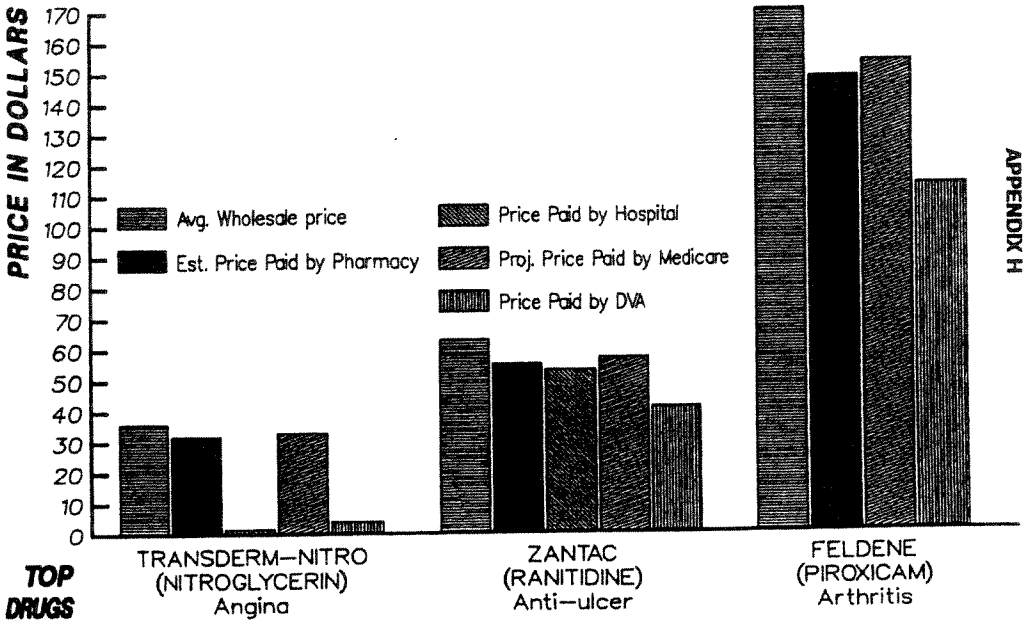
28

APPENDIX G



29

Range of Market Prices Paid for Single Source Prescription Drugs: Spring 1989



APPENDIX H

30

RANGE OF MARKET PRICES PAID FOR BRAND NAME PRESCRIPTION DRUGS, SPRING 1989
(Ten Products Representing Approximately 8% of Prescriptions for the Elderly)

DRUG	STRENGTH, PKG. SIZE	INDICATION	PUBLISHED MFR'S AVG. WHOLESALE PRICE	ESTIMATED PRICE PAID BY PHARMACY	PRICE PAID BY HOSPITALS	HOSPITAL SAVINGS BELOW PHARMACY	PROJECTED PRICE PAID BY MEDICARE IF IN EFFECT	PRICE PAID BY DEPT. OF VETERANS AFFAIRS (DVA)	DVA SAVINGS BELOW MEDICARE
CARDIZEM (DILTIAZEM)	60 mg, 100 tabs	Chest Pain, High B.P.	$47	$41	N/A	N/A	$42	$33	21%
LOPRESSOR (METOPROLOL)	50 mg, 100 tabs	Chest Pain, High B.P.	$36	$32	$28	13%	$33	$24	27%
PROCARDIA (NIFEDIPINE)	10 mg, 300 caps	Chest Pain, High B.P.	$115	$100	N/A	N/A	$103	$76	26%
TENORMIN (ATENOLOL)	50 mg, 100 tabs	Chest Pain, High B.P.	$59	$51	$45	12%	53%	$39	26%
TRANSDERM-NITRO (NITROGLYCERIN)	5 mg, 30 patches	Chest Pain	$36	$32	$.01	99%	$33	$4	88%
CAPOTEN (CAPTOPRIL)	25 mg, 100 tabs	High B.P.	$42	$37	N/A	N/A	$39	$32	18%
PEPCID (FAMOTIDINE)	40 mg, 30 tabs	Anti-ulcer	$63	$55	N/A	N/A	$57	$50	12%
TAGAMET (CIMETIDINE)	300 mg, 100 tabs	Anti-ulcer	$55	$48	$39	19%	$49	N/A	N/A
ZANTAC (RANITIDINE)	300 mg, 30 tabs	Anti-ulcer	$63	$55	$53	4%	$57	$41	28%
FELDENE (PIROXICAM)	20 mg, 100 tabs	Arthritis	$170	$148	N/A	N/A	$153	$113	26%

APPENDIX I

31

APPENDIX J

Examples of letters of refusal from prescription drug manufacturers to a multi-state pharmacy buying group, in response to the buying group's request for pricing bids.

BRISTOL-MYERS
U.S. PHARMACEUTICAL AND NUTRITIONAL GROUP
EVANSVILLE, INDIANA 47721-0001 TELEPHONE (812)429-5000

July 20, 1988

Pace Alliance, Inc.
Retail Pharmacy Purchasing Group
600 Lawrence Avenue, Suite 2A
Lawrence KS 66044

Gentlemen:

This will acknowledge receipt of your request dated July 14, 1988. We are pleased to have been selected by Pace Alliance, Inc. and offered an opportunity to bid. I regret, however, that at this time we are unable to comply with your request.

Current Company policy precludes our instituting bid prices with customers other than those within the already established approved guidelines. Pace Alliance, Inc. does not presently fall within those parameters.

The pharmaceutical industry, however, is undergoing a great deal of change and Mead Johnson/Bristol-Myers is no exception. Our customer policy has never been subject to more intensive evaluation than at this time, and if a policy change should result which would impact favorably on your request, you will be notified immediately.

In the interim, if I can ever be of service, please don't hesitate to call.

Sincerely,

M. J. Walts
Supervisor, Pricing

MJW/bb
enc.

Glaxo

Glaxo Inc

July 27, 1988

Mr. Curtis J. Woods, R.Ph.
Vice President
Pace Alliance, Inc.
600 Lawrence Avenue
Suite 2A
Lawrence, KS 66044

Dear Mr. Woods:

Thank you for your solicitation for special pricing. Currently our policy at Glaxo is not to bid to retail pharmacies or retail pharmacy buying groups. Should our position change in the future, we will be happy to work with you.

Please accept our apologies and thank you for your interest in Glaxo.

Sincerely,

Dennis J. Dial
Group Manager
Pricing Development and Contracts

DJD/ct

cc: Ted Kambour
Nancy Benevento

Five Moore Drive P.O. Box 13358 Research Triangle Park, NC 27709 • Telex 802813 • Telephone (919) 248-2100

MARION LABORATORIES, INC.

P.O. BOX 8480 • KANSAS CITY, MISSOURI 64114-0480 • 816-966-4000

July 19, 1988

Pace Alliance, Inc.
Retail Pharmacy Purchasing Group
600 Lawrence Ave., Suite 2A
Lawrence, KS 66044

Attention: Mr. B.K. Wyatt, RPh, President/CEO

Gentlemen:

We have received your invitation to offer quotations on a number of Marion products.

We will be unable to offer a quotation at this time as our current bidding policy precludes our offering quotations to organizations such as yours. Because the world of healthcare is undergoing many rapid changes, we are attempting to examine all options and avenues for distribution of our products before changing any of our present policies. At this time, therefore, we must respectfully decline your invitation to bid.

Thank you for contacting us.

Sincerely,

MARION LABORATORIES, INC.

Alfred A. Mannino
Vice President
Corporate Affairs

JDT/rk

788a/9

PARKE-DAVIS
Division of Warner-Lambert Company

July 19, 1988

Dr. Curtis J. Woods, R.Ph.
Pace Alliance, Inc.
600 Lawrence Avenue
Suite 2A
Lawrence, KS 66044

Dear Dr. Woods:

Thank you for the opportunity to bid on the annual pharmaceutical requirements of Pace Alliance, Inc. We regret to advise you that Parke-Davis policy precludes our entering into such an arrangement at this time.

We appreciate the opportunity and thank you for your continued interest in Parke-Davis.

Sincerely,

Lisa M. Recchia
Supervisor, Pricing

LMR:atv

cc: R. J. Banchanska
A. A. Bonelli
M. E. Moran
J. T. Roberts

Roche Laboratories
a division of Hoffmann-La Roche Inc.

340 Kingsland Street
Nutley, New Jersey 07110-1199

Direct Dial

July 20, 1988

Curtis J. Woods, R.Ph.
Vice President
Pace Alliance, Inc.
600 Lawrence Avenue, Suite 2A
Lawrence, KS 66044

Dear Mr. Woods:

Thank you for your recent invitation to bid on various pharmaceuticals.

Current policy does not permit us to offer prices to your trade category at this time. However, we would like to remain on your bidders mailing list should our policy change.

We appreciate your interest in Roche pharmaceuticals, if we may be of any further assistance, please do not hesitate to contact us.

Sincerely,

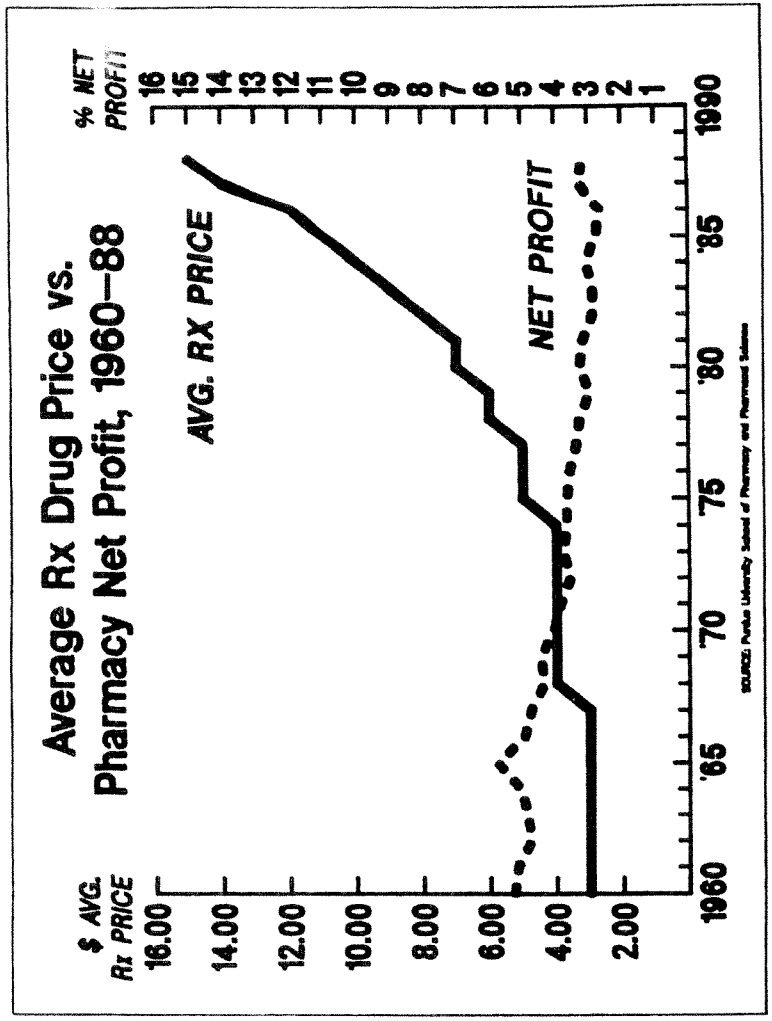
Jacqueline Sutton

Jacqueline H. Sutton
Administrator,
Pharmaceutical Bids & Contracts

JHS/ls

cc: S. Cofoni w/attachment
M. Goodson " "
J. Henry " "

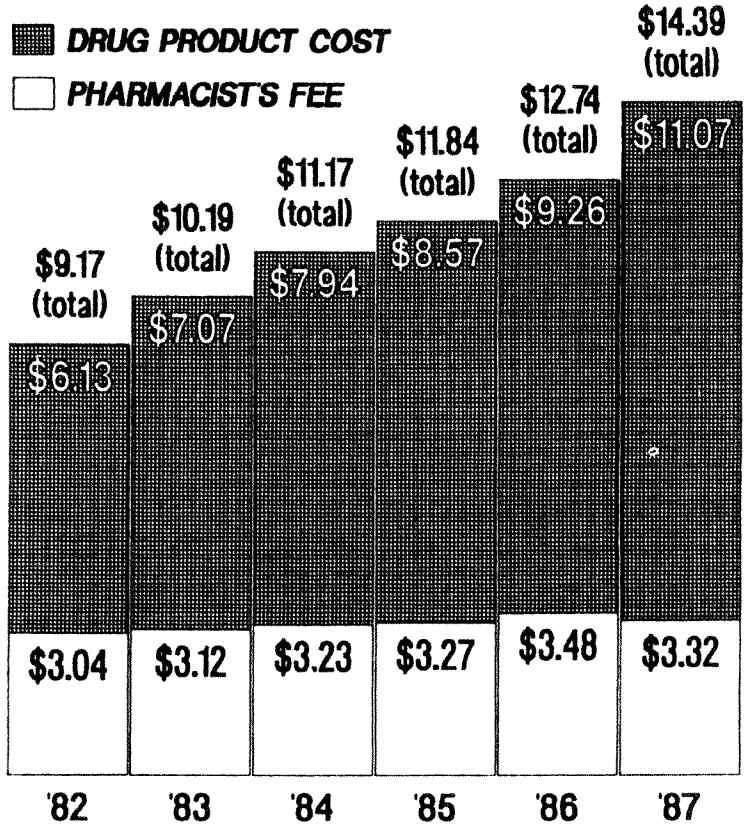
APPENDIX K



APPENDIX L

Cutting Reimbursement Hurts Pharmacies Without Affecting Drug Prices

Medicaid Rx Drug Reimbursement Components, 1982–87



SOURCE: Compiled by the Pharmaceutical Economics Research Center, Purdue University, from data found in Benefits, Under State Medical Assistance Programs, Reston, VA: National Pharmaceutical Council, various years.

APPENDIX M

Congressional Research Service
The Library of Congress

Washington, D.C. 20540

July 13, 1989

TO : Senate Special Committee on Aging
Attention: John Monahan

FROM : American Law Division

SUBJECT : Analysis of Government Use of Patented Pharmaceuticals

INTRODUCTION

Various questions have been raised concerning the government's possible use or manufacture of patented pharmaceuticals without the permission of the patent holder.[1] Foremost among these questions is what recourse the patent holder might pursue against the federal government. Directly related questions involve how such actions have been maintained and what factors have been considered by the courts in their resolution of such issues. This memorandum analyzes the remedy that a patent holder might have against the federal government if the federal government attempts to use the patent holder's pharmaceutical patent without his/her permission.

It appears that the fundamental recourse available to such a patent holder in this situation is specifically authorized by a federal statute which provides that the patent owner's remedy shall be an action against the United States in the United States Claims Court for the recovery of the "reasonable and entire compensation" for such use.[2] The legislative development and the judicial application and interpretation of this statute are discussed below.[3]

[1] Such a situation might arise through the federal government's attempt to reduce costs of federal drug purchase/reimbursement programs by "taking" the drug patent. However, during the term of the drug's patent, usually seventeen years, the law permits only the patent holder to produce or to license another manufacturer to produce the drug. The government might have another manufacturer produce the "single-source drugs" (chemical entities for which only the patented product is available) at a reduced cost. In such a situation, the government might be using/taking the patent without the permission of the patent holder and could be subject to an action brought by the patent holder. See, letter from John Monahan, Senate Special Committee on Aging, to Douglas Weimer, CRS (July 6, 1989).

BACKGROUND

It is well-established that, when a patent is granted for a discovery, it confers upon the patentee the sole rights to the patent (35 U.S.C. § 154(1982)) and that it cannot be used, taken, or appropriated by the government or its agent without just compensation (U.S. Const. amend V).[4] Courts and Congress have determined that the only remedy available under an eminent domain[5] taking of a license in a patent is through a specific federal statute which provides relief in the United States Claims Court (28 U.S.C. § 1498(1982)).[6] It has been held that section 1498 "authorizes the Government to take, through exercise of its power of eminent domain, a license in any United States patent."[7] This statutory remedy was enacted in 1910 in order to provide patent owners with recourse for reasonable compensation for the use of patents by the government without the license or the permission of the owner to use the patented discovery.[8] Although the statute has been modified various times, its primary remedy has remained constant.

[2] 28 U.S.C. § 1498(a)(1982)(copy in Appendix).

[3] This memorandum summarizes several telephone discussions and a staff meeting between Douglas Weimer of the American Law Division and John Monahan of the Senate Special Committee on Aging.

[4] *See*, Rosenberg, *Patent Law Fundamentals* § 12.4[3](1988).

[5] The concept of eminent domain involves a "taking" by the sovereign government of private property for the public good. Such private property may be real or personal. *See, Boom Co. v. Patterson*, 98 U.S. 403 (1879). Examples of private property taken through eminent domain proceedings could involve real property, the franchise of a private corporation, or letters patent for a new invention. *See, e.g., James v. Campbell*, 104 U.S. 356 (1882); *Hollister v. Benedict Mfg. Co.*, 113 U.S. 59 (1885).

[6] *Decca, Ltd. v. United States*, 640 F.2d 1156, 1166 (Ct.Cl. 1980).

[7] *Id.*

[8] Act of June 25, 1910, C. 423, 36 Stat. 851.

§ 1498. Patent and copyright cases

(a) Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Claims Court for the recovery of his *reasonable and entire compensation* for such use and manufacture. (emphasis added)

* * * * [9]

It appears that this statute ("section 1498") would probably govern remedies pursued by pharmaceutical manufacturers who seek relief against unauthorized government use of their patents. Thus, the patent holder(s) would bring an action against the government in the United States Claims Court ("court.")[10] The court would then analyze the situation and determine whether a patent had been used without the permission of the owner and further determine the *reasonable and entire* compensation to be awarded to the patent holder.

ANALYSIS

Since its enactment in 1910, section 1498 has been subject to extensive judicial scrutiny and review. Although it does not appear that there has been a case involving the government's "taking" of a pharmaceutical patent, various other cases involving the government's uses of patented processes and devices provide precedent and guidance for a judicial review of a pharmaceutical "taking." Initially, the Court of Claims and, after 1982, the Claims Court scrutinized various situations involving governmental use of patented processes and determined whether the federal government had indeed "taken" a patent. If a "taking" was determined to have occurred, the courts would calculate the plaintiff's "reasonable and entire" compensation for such a use or taking.

An analysis of several key cases involving claims brought concerning federal use of patented devices/processes provides insight into the judicial reasoning and determinations resulting in the award of damages to the patent

[9] 28 U.S.C. § 1498(a)(1982).

[10] Prior to the 1982 amendments (Pub. L. 97-164, title I, § 133(d)(1), Apr. 2, 1982, 96 Stat. 40), remedies for the taking of private patent rights by the federal government were brought in the United States Court of Claims.

holder. Most of the cases present two questions: first, was there a government "taking or use" of the patent; and second, if so, what is the "reasonable and entire" compensation which the patent holder is entitled to by section 1498.[11]

Early cases considered the parameters of "reasonable and entire" compensation. In a 1931 case, the Supreme Court held that interest would be permitted when determining the extent of the damages assessed against the federal government.[12] In another early and important case, *Marconi Wireless Telegraph Company of America v. United States*, [13] the court devised a licensing or leasing approach in its determination of a suitable settlement to the patent holder. In resolving what was "reasonable and entire" compensation, the court undertook detailed and complex accounting procedures, as well as comparative market approaches. After an extensive examination of licensing procedures, the court determined that the patent holder was entitled to a 10% "licensing" fee-type compensation from the government. This royalty or licensing fee represented 10% of the selling price or market value of the actual patented products.[14] In the *Fauber* case,[15] the court adopted a similar accounting-type approach and also provided an interest payment for the patent holder. In this case, a 4% royalty was assessed on the market value of each manufactured product which was "taken" by the federal government. [16]

Later cases also adopted detailed accounting and investigative procedures in determining "reasonable and entire" compensation for the patent holder. Market conditions and comparative licensing arrangements were examined by the courts, as well as prevailing interest rates. In *Pitcairn*,[17] the court examined at great length the concept of a "taking" of a patented device by the

[11] *See*, Lipscomb, *Lipscomb's Walker on Patents* § 22:22 (1987).

[12] *Waite v. United States*, 282 U.S. 508 (1931).

[13] 99 Ct.Cl. 1 (1942), *modified on other grounds*, 320 U.S. 1 (1943), *reh'g denied*, 320 U.S. 809 (1943).

[14] *Id.*, at 22. The court computed the entire market value of the patented apparatus and determined that the reasonable and entire compensation was 10% of the market value of the devices which were actually "taken" by the federal government. *Id.*

[15] *Fauber v. United States*, 81 F.Supp. 218 (Ct.Cl. 1948), *cert. denied*, 337 U.S. 906 (1949).

[16] *Id.*, at 219.

[17] *Pitcairn v. United States*, 547 F.2d 1106 (Ct.Cl. 1976), *cert. denied*, 434 U.S. 1051 (1978).

government and characterized this taking as a license in the patent. The court also articulated the concept of "delay compensation," the payment to the patent holder for the wait or delay in receiving compensation.[18] The court adopted the willing buyer-willing seller approach in computing compensation in the *Tektronix* case.[19] In reaching its estimation of "reasonable and entire" compensation, the court tried to establish the marketplace within the context of its judicial determination. After its review of the "marketplace," the court based its 10% royalty on its best judgment of what reasonable parties might have agreed upon in the open market in a licensing arrangement. The court characterized a "reasonable royalty" as a "device in aid of justice," whereby something incalculable is approximated.[20]

Another case of considerable importance in the determination of damages under section 1498 actions was *Leesona Corp. v. United States*.[21] This case examined the damages which a plaintiff could secure against the United States. In this action, the damage award had initially been based upon a tort claim, rather than under the theory of eminent domain under section 1498.[22] It appears that recovery under section 1498 on the basis of a tort theory was unique and was ultimately rejected by the Court of Claims.[23] Research has not discovered any later cases basing an award upon the tort theory. Furthermore, the plaintiff sought multiple damages and attorney fees. The Court of Claims determined that a comparative royalty technique was the preferred method for determining just compensation.[24] "The proper measure in eminent domain is what the owner has lost, not what the taker has gained."[25] The court specifically rejected the concept of double damages, based

[18] *Id.*, at 1120 *et. seq.*

[19] *Tektronix, Inc v. United States*, 552 F.2d 343 (Ct.Cl. 1977), *reh'g denied*, 557 F.2d 265 (Ct.Cl. 1977).

[20] 552 F.2d 343, 351 (Ct Cl. 1977).

[21] 599 F.2d 958 (Ct.Cl. 1979).

[22] In a prior action, *Leesona Corp. v. United States*, 530 F.2d 896 (Ct.Cl. 1976), the Court of Claims had held that three patents owned by Leesona were valid and had been infringed by the United States. The Court of Claims then referred the "accounting phase" of the action to Trial Judge Browne who based his damages upon a tort theory of recovery. 599 F.2d 958, 962 (Ct.Cl. 1979). The Court of Claims reconsidered the damages determined in the "accounting phase" and set aside the findings of Trial Judge Browne. *Id.*

[23] *Id.*, at 962.

[24] *Id.*, at 967 *et. seq.*

[25] *Id.*, at 969.

upon the government's alleged bad faith.[26] Another issue which *Leesona* clarified was the rejection of an additional damage award to the plaintiff based upon savings to the federal government through the use of plaintiff's patent.[27] However, the court held that savings to the government could be considered in the determination of "reasonable compensation."[28] Thus, this case set forth important principles in the determination of compensation: damages should be based upon an eminent domain theory rather than upon a tort claim; plaintiffs were not to be awarded multiple damages and attorney fees; and plaintiffs were not entitled to a special award based upon government savings, although such savings could be considered in the determination of reasonable compensation. Thus, *Leesona* set forth the principle that damages under section 1498 actions should be based upon the theory of eminent domain, rather than upon the basis of tort claims.

Applying the principles provided by *Leesona*, the court in *Bendix Corp. v. United States*[29] determined that the proper measure of damages was through a determination of damages based upon the theory of eminent domain.

> Because 28 U.S.C. § 1498 permits the government to take a license, through exercise of its eminent domain power, in any United States patent, we concluded that the government had taken a royalty-bearing license in plaintiff's patent.[30]

Based upon this concept, the court determined what would be a reasonable recovery based upon a royalty theory. The court also awarded delay compensation.[31]

In considering the possible recovery that a pharmaceutical patent plaintiff could receive, several principles can be gleaned from the above cases. First, the court must determine whether a "taking" of a patent has occurred. It appears likely from the hypothetical fact situation described in footnote one that the court would determine that a taking had occurred. The court's next task is to compute "reasonable and entire" compensation. In its computation of such compensation, the court would probably consider the government use under a theory of taking or eminent domain, rather than under a tort theory.

[26] *Id.*

[27] *Id.*, at 971.

[28] *Id.*

[29] 676 F.2d 606 (Ct.Cl. 1982).

[30] *Id.*, at 607.

[31] *Id.*, at 615.

Under the eminent domain theory, the court would probably try to determine a licensing approach[32] to determine what sort of licensing fee the patent holder would have received on the open market. Although the plaintiff could not recover a specific award based upon the savings that the government may have received through the use of his/her patent, such savings would probably be considered in the basis for the licensing award. Upon the basis of *Leesona*, the court would probably not permit multiple or punitive damages and the plaintiff probably would not be eligible for the recovery of attorneys' fees and other expenses. Thus, the court would probably try to calculate a licensing fee based upon prevailing market conditions and base damages upon this licensing fee.[33] In addition, the court could also award delay compensation to the plaintiff.

CONCLUSION

Congress has provided a means to compensate patent holders whose patents have been "taken" by the federal government through section 1498. Such compensation is required by the statute to be "reasonable and entire." Through the years, courts have determined the meaning of this requirement in very specific situations. Numerous aspects of a case have been considered by the court in its attempt to award damages. Although it does not appear that there has been an action brought under the section for pharmaceutical use, existing case law provides guidance as to what courts might consider in such an action. Most likely, the court would approach the issue of damages through a licensing approach, rather than upon a tort theory. It is speculative to attempt to determine what a court would consider to be "reasonable and entire" compensation in a pharmaceutical case, but other taking cases in the patent area have set forth guidelines which establish possible parameters for the awarding of damages in the instant situation.

Douglas Reid Weimer
Legislative Attorney

---

[32] The court might base a licensing percentage upon the fair market price or value of the infringed products.

[33] See, Chisum, *Patents* § 1606[3](Vol. 4)(1988 Supp.)

APPENDIX

EFFECTIVE DATE OF 1982 AMENDMENT

Amendment by Pub. L. 97-164 effective Oct. 1, 1982, see section 402 of Pub. L. 97-164, set out as a note under section 171 of this title.

CROSS REFERENCES

Procedure on claims for damages for unjust conviction and imprisonment, see section 2513 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 2513 of this title.

§ 1496. Disbursing officers' claims

The United States Claims Court shall have jurisdiction to render judgment upon any claim by a disbursing officer of the United States or by his administrator or executor for relief from responsibility for loss, in line of duty, of Government funds, vouchers, records or other papers in his charge.

(June 25, 1948, ch. 646, 62 Stat. 941; Apr. 2, 1982, Pub. L. 97-164, title I, § 133(c)(1), 96 Stat. 40.)

HISTORICAL AND REVISION NOTES

Based on title 28, U.S.C., 1940 ed., § 250(3) (Mar. 3, 1911, ch. 231, § 145, 36 Stat. 1136; June 10, 1921, ch. 18, § 304, 42 Stat. 24).

Words "paymaster, quartermaster, commissary of subsistence, or other," preceding "disbursing officer of the United States," were omitted. See *Henderson v. United States*, 1907, 42 Ct.Cl. 449 and *Hobbs v. United States*, 1881, 17 Ct.Cl. 189, holding that the term "other disbursing officer" extends to any disbursing officer of the executive departments of the Government.

Words "by capture or otherwise" were omitted as surplusage.

Words "and for which such officer was and is held responsible," at the end of section 250(3) of title 28, U.S.C., 1940 ed., were omitted as surplusage.

Changes were made in phraseology.

AMENDMENTS

1982—Pub. L. 97-164 substituted "United States Claims Court" for "Court of Claims".

EFFECTIVE DATE OF 1982 AMENDMENT

Amendment by Pub. L. 97-164 effective Oct. 1, 1982, see section 402 of Pub. L. 97-164, set out as a note under section 171 of this title.

CROSS REFERENCES

Allowance of credit in settlement of disbursing officers' accounts, see section 2512 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in title 41 section 114.

§ 1497. Oyster growers' damages from dredging operations

The United States Claims Court shall have jurisdiction to render judgment upon any claim for damages to oyster growers on private or leased lands or bottoms arising from dredging operations or use of other machinery and equipment in making river and harbor improvements authorized by Act of Congress.

(June 25, 1948, ch. 646, 62 Stat. 941; Apr. 2, 1982, Pub. L. 97-164, title I, § 133(c), 96 Stat. 40.)

HISTORICAL AND REVISION NOTES

Based on title 28, U.S.C., 1940 ed., § 250a (Aug. 30, 1935, ch. 831, § 13, 49 Stat. 1049; July 13, 1943, ch. 231, 57 Stat. 553).

The proviso at the end of section 250a of title 28, U.S.C., 1940 ed., is incorporated in section 2501 of this title.

Words "river and harbor improvements" were substituted for "such improvements", in view of Dixon v. U.S., 103 Ct. Cl. 160, holding that words, "such improvements" were not limited to the specific improvements listed in the 1935 act, but applied to any river and harbor improvements.

Changes were made in phraseology.

AMENDMENTS

1982—Pub. L. 97-164 substituted "growers'" for "growers," in the section catchline, and in text substituted "United States Claims Court" for "Court of Claims".

EFFECTIVE DATE OF 1982 AMENDMENT

Amendment by Pub. L. 97-164 effective Oct. 1, 1982, see section 402 of Pub. L. 97-164, set out as a note under section 171 of this title.

CROSS REFERENCES

Time for filing petition by oyster growers, see section 2501 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 2501 of this title.

§ 1498. Patent and copyright cases

(a) Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Claims Court for the recovery of his reasonable and entire compensation for such use and manufacture.

For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.

The court shall not award compensation under this section if the claim is based on the use or manufacture by or for the United States of any article owned, leased, used by, or in the possession of the United States prior to July 1, 1918.

A Government employee shall have the right to bring suit against the Government under this section except where he was in a position to order, influence, or induce use of the invention by the Government. This section shall not confer a right of action on any patentee or any assignee of such patentee with respect to any invention discovered or invented by a person while in the employment or service of the United States, where the invention was related to the official functions of the employee, in cases in which such functions included research and development, or in the making of which

Government time, materials or facilities were used.

(b) Hereafter, whenever the copyright in any work protected under the copyright laws of the United States shall be infringed by the United States, by a corporation owned or controlled by the United States, or by a contractor, subcontractor, or any person, firm, or corporation acting for the Government and with the authorization or consent of the Government, the exclusive remedy of the owner of such copyright shall be by action against the United States in the Claims Court for the recovery of his reasonable and entire compensation as damages for such infringement, including the minimum statutory damages as set forth in section 504(c) of title 17, United States Code: *Provided*, That a Government employee shall have a right of action against the Government under this subsection except where he was in a position to order, influence, or induce use of the copyrighted work by the Government: *Provided, however*, That this subsection shall not confer a right of action on any copyright owner or any assignee of such owner with respect to any copyrighted work prepared by a person while in the employment or service of the United States, where the copyrighted work was prepared as a part of the official functions of the employee, or in the preparation of which Government time, material, or facilities were used: *And provided further*, That before such action against the United States has been instituted the appropriate corporation owned or controlled by the United States or the head of the appropriate department or agency of the Government, as the case may be, is authorized to enter into an agreement with the copyright owner in full settlement and compromise for the damages accruing to him by reason of such infringement and to settle the claim administratively out of available appropriations.

Except as otherwise provided by law, no recovery shall be had for any infringement of a copyright covered by this subsection committed more than three years prior to the filing of the complaint or counterclaim for infringement in the action, except that the period between the date of receipt of a written claim for compensation by the Department or agency of the Government or corporation owned or controlled by the United States, as the case may be, having authority to settle such claim and the date of mailing by the Government of a notice to the claimant that his claim has been denied shall not be counted as a part of the three years, unless suit is brought before the last-mentioned date.

(c) The provisions of this section shall not apply to any claim arising in a foreign country.

(d) Hereafter, whenever a plant variety protected by a certificate of plant variety protection under the laws of the United States shall be infringed by the United States, by a corporation owned or controlled by the United States, or by a contractor, subcontractor, or any person, firm, or corporation acting for the Government, and with the authorization and consent of the Government, the exclusive remedy of the owner of such certificate shall be by action against the United States in the Claims Court for the recovery of his reasonable and entire compensation as damages for such infringement: *Provided*, That a Government employee shall have a right of action against the Government under this subsection except where he was in a position to order, influence, or induce use of the protected plant variety by the Government: *Provided, however*, That this subsection shall not confer a right of action on any certificate owner or any assignee of such owner with respect to any protected plant variety made by a person while in the employment or service of the United States, where such variety was prepared as a part of the official functions of the employee, or in the preparation of which Government time, material, or facilities were used: *And provided further*, That before such action against the United States has been instituted, the appropriate corporation owned or controlled by the United States or the head of the appropriate agency of the Government, as the case may be, is authorized to enter into an agreement with the certificate owner in full settlement and compromise, for the damages accrued to him by reason of such infringement and to settle the claim administratively out of available appropriations.

(June 25, 1948, ch. 646, 62 Stat. 941; May 24, 1949, ch. 139, § 87, 63 Stat. 102; Oct. 31, 1951, ch. 655, § 50(c), 65 Stat. 727; July 17, 1952, ch. 930, 66 Stat. 757; Sept. 8, 1960, Pub. L. 86-726, §§ 1, 4, 74 Stat. 855, 856; Dec. 24, 1970, Pub. L. 91-577, title III, § 143(d), 84 Stat. 1559; Oct. 19, 1976, Pub. L. 94-553, title I, § 105(c), 90 Stat. 2599; Apr. 2, 1982, Pub. L. 97-164, title I, § 133(d), 96 Stat. 40.)

HISTORICAL AND REVISION NOTES

1948 ACT

Based on section 68 of title 35, U.S.C., 1940 ed., Patents (June 25, 1910, ch. 423, 36 Stat. 851; July 1, 1918, ch. 114, 40 Stat. 705).

Provisions contained in the second proviso of section 68 of title 35, U.S.C., 1940 ed., relating to right of the United States to any general or special defense available to defendants in patent infringement suits were omitted as unnecessary. In the absence of statutory restriction, any defense available to a private party is equally available to the United States.

Changes in phraseology were made.

1949 ACT

This amendment clarifies section 1498 of title 28, U.S.C., by restating its first paragraph to conform more closely with the original law.

REFERENCES IN TEXT

Hereafter, referred to in subsec. (b), probably means the date of enactment of Pub. L. 86-726, which was approved on Sept. 8, 1960.

The copyright laws of the United States, referred to in subsec. (b), are classified generally to Title 17, Copyrights.

Hereafter, referred to in subsec. (d), probably means after the date of enactment of Pub. L. 91-577, which was approved on Dec. 24, 1970.

AMENDMENTS

1982—Subsec. (a). Pub. L. 97-164, § 133(d)(1), substituted "United States Claims Court" for "Court of Claims"